

**REMARKS**

Claims 124-129 are pending in this application. Claims 124 and 127 are amended to recite heating temperatures of about 230°C to about 300°C. Claims 125 and 128 are amended to recite heating temperature of about 230°C and about 300°C, respectively. Support for the amendment can be found throughout the specification, for example, see original specification pages 20, 30, 89 and 91 and original claims 88 and 89. Therefore, no new matter is introduced. The Office Action is discussed below:

***Anticipation Rejection and Response to Arguments:***

On pages 2-5 of the office action, the examiner has maintained the alleged anticipation rejection of claims 124-129 in view of Dijkstra *et al.* ("Crosslinking of Ultra-high Molecular Weight Polyethylene in the Melt by Means of Electron Beam Irradiation" published May, 1989) and claims 127-129 in view of Hyon *et al.* (U.S. 6,168,626, filed May 6, 1996).

On page 2 of the Office Action, the examiner has responded that:

"With respect to applicant's arguments about continued heating when a sample is outside the e beam, this feature is not disclosed with any specificity in the instant specification. Nor is heating prior to each irradiation dose or irradiation after each irradiation dose disclosed with any specificity in the instant specification as filed. If applicant intended to claim such a process, the process should have been clearly described in the specification as filed. There is no recognition noted that the process as now claimed was disclosed as the inventive concept in the specification as originally filed."

Applicants respectfully disagree and submit that the examiner has not addressed the responses and arguments provided in the previous responses, including the response filed on March 15, 2010. The examiner has continued to assert that the arguments of what is inherent to the disclosure are unpersuasive and has not considered the dictates of the MPEP that states:

**"A CLAIM TERM WHICH HAS NO ANTECEDENT BASIS IN THE DISCLOSURE IS NOT NECESSARILY INDEFINITE"**

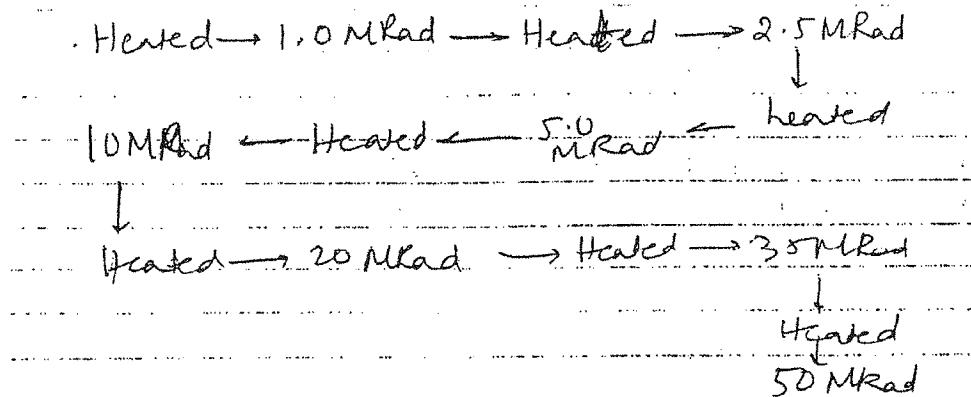
The mere fact that a term or phrase used in the claim has no antecedent basis in the specification disclosure does not mean, necessarily,

that the term or phrase is indefinite. There is no requirement that the words in the claim must match those used in the specification disclosure. Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision."

See MPEP § 2173.05(e) (Rev. 6, September 2007 at page 2100-225).

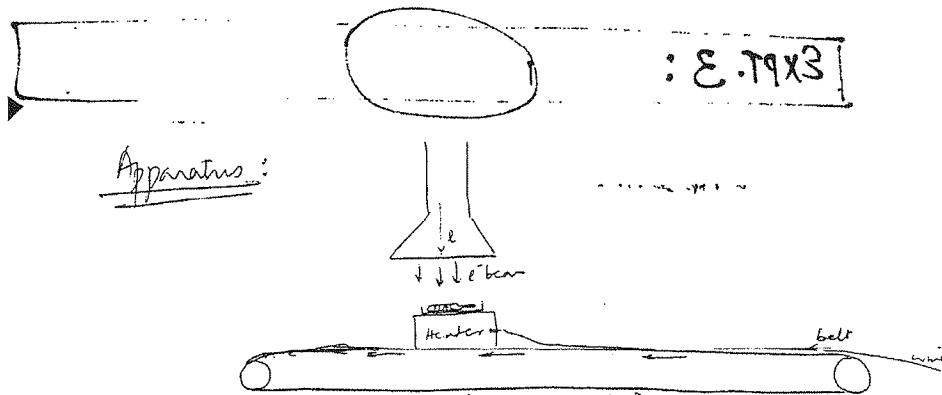
Applicants request the examiner to consider the response filed in the parent application (Serial No. 10/197,209) regarding irradiation by van de Graaff generator (see pages 5-7 of the response filed May 14, 2008), that when the sample moves outside the e-beam the sample does not receive any radiation dose. However, since the heating continued when the sample is outside of the e-beam, the sample receives heating before each dose of irradiation. Also, the sample is irradiated after each heating. In other words, radiation is not applied to the sample when the sample is moved outside the e-beam. Thus, the sample is heated prior to the next dose of irradiation and also heated after each dose of irradiation.

Applicants also request the examiner to considering Dr. Orhun Muratoglu's declaration submitted in a related application, Serial No. 11/184,803. In the declaration, Dr. Muratoglu reviewed the Rule 1.131 declaration, filed on July 16, 2004, and found that Exhibit 3 of the declaration clearly shows that the Experiment 2 describes step by step process of irradiation, pause or cease in-between the passes, heating the consolidated polymer in-between the steps, and continued irradiation until a total dose of up to 50 Mrads is attained (see below, as reproduced from the Exhibit 3):



Applicants point out, Dr. Muratoglu also found that Exhibit 3 of the declaration

depicts a sketch of the van de Graaff generator as the radiation source and a consolidated polymer on the conveyer belt passing under the radiation source (see below for the sketch as shown in Experiment 4, source: Exhibit 3 of the declaration):



This depiction shows the irradiation step using van de Graaff generator in the Experiment 4 (also, see enclosed photographs of a common van de Graaff generator in Exhibits 1-4 as filed with the previous response of July 9, 2009).

The sample receives no radiation dose when it is outside of the e-beam radiation station and continues to move on the conveyer belt until it is put back on the entry end of the belt for a second dose. The process is repeated to obtain a total dose of 5 Mrad or more, because the van de Graaff generator provides a dose of 2.5 Mrad per pass per pass in this experiment. The van de Graaff generator can also be adjusted to deliver higher or lower radiation doses per pass. It is therefore clear to the skilled persons and lay persons alike from the above sketch that there is a pause or the radiation ceases when sample passes out of the radiation zone and the steps of radiation and ceasing radiation are repeated with heating after each dose of radiation until the desired total dose is received by the sample.

In this context, applicants request the examiner to consider the dictates of the MPEP that:

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that

defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

See MPEP § 2173.04 (Rev. 6, September 2007 at 2100-220).

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973).

See MPEP § 2163.07(a) (Rev. 6, September 2007 at 2100-192).

On pages 2-3 of the Office Action, the examiner has referred that Dijkstra *et al.* are also familiar with a van de Graaff generator, then the disclosure of Dijkstra *et al.* also inherently discloses repetitions during the irradiation process to achieve a desired radiation dose. Applicants pointed out this in the response filed on March 15, 2009 (see page 5 of the response) that Dijkstra *et al.* are familiar with the van de Graaff generator (see Dijkstra *et al.* page 866, col. 2) and referred to their previous reference (see Dijkstra *et al.* 1987 Polym. Bull. 17, p.507) regarding the process of a van de Graaff generator, as known in the art. Therefore, it is evident that the argued process is clear to one skilled in the art. However, Dijkstra *et al.* do not anticipate the claimed invention, as clarified in the previous response (see page 7 of the response filed on March 15, 2010), because the instant claims recite heating the preform to a temperature above the melting point of the UHMWPE to about 230°C (see claim 124) or more (for example, 300°C in claim 127). Thus, Dijkstra *et al.* does not disclose all claim limitations as recited in the claims in order to anticipate the claimed invention.

Yet, at the end of page 3 of the Office Action, the examiner contends that 200°C temperature described in Dijkstra is within each of the ranges recited in the claims. Without acquiescing in the examiner's rejection, in order to expedite the prosecution and to further distinguish the claimed invention from the cited reference, applicants amend claims 124 and 127 to recite heating temperatures of about 230°C to about 300°C. Support for the amendment can be found throughout the specification. For

example, see original specification pages 20, 30, 89 and 91 and original claims 88, 89 and 91.

Regarding Dijkstra *et al.* disclosure, applicants also point out that Dijkstra discloses a process for making bar stocks of polyethylene and does not relate to a method for making an orthopaedic implant according to the claimed invention. Therefore, Dijkstra *et al.* publication is not relevant to the claimed invention. See MPEP § 2111.02.

Applicants also submit that the instantly claimed elements "a process for preparing an orthopaedic implant prosthesis bearing" using "heat treatment" and "irradiation" are not expressly or inherently disclosed in Dijkstra *et al.* Applicants refer the examiner to MPEP § 2131 (Rev. 6, September 2007) that:

"[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Accordingly, applicants point out that Dijkstra *et al.* do not anticipate the claimed invention.

Regarding the priority claim, applicants refer to the Rule 1.131 declaration of Merrill *et al.*, filed June 8, 2007, and the clarifications as filed with the previous response, filed March 15, 2010 that the evidence presented shows reduction to practice of the instantly claimed methods before January 20, 1995. It also was evident that the polyethylene was first melted and then irradiated (see the Declaration of Merrill *et al.*, sections 10-11 and item b of Exhibit 1, for example), which sufficiently provides the evidence of reduction to practice of the claimed method. Hence, a method that involves irradiation is followed by subsequent melting to treat a polyethylene preform was reduced to practice before January 20, 1995. Accordingly, Hyon is not a prior art to the claimed invention.

On page 3 of the Office Action, the examiner opines that in the Declaration the statement "b" "crosslink as solid, melt, recrystallize" under Basic Motivation in Exhibit 1 is a statement of intent to explore but not evidence of a reduction to practice.

Applicants disagree with the examiner and submit that the examiner has misconstrued the Rule 1.131 Merrill declaration and has not addressed the above arguments and the clarifications. Applicants point out, as the MPEP instructs:

The Examiner must then weigh all the evidence before him or her, including the specification and any new evidence supplied by applicant with the evidence and/or sound scientific reasoning previously presented in the rejection and decide whether the claimed invention is enabled. The Examiner should never make the determination based upon personal opinion. The determination should always be based on the weight of all the evidence.

See MPEP § 2164.05 (Rev. 6, September 2007 at 2100-199) (emphasis in original).

Applicants refer the examiner to Dr. Orhun Muratoglu's declaration in a related application 11/184,803, as discussed above, in which Dr. Muratoglu reviewed Rule 1.131 Merrill declaration, and found that Irradiation and Subsequent Melting embodiment was conceived and reduced to practice prior to January 20, 1995.

In view of the above clarifications and amendments to the claims, applicants submit that Dijkstra *et al.* and Hyon *et al.* are not prior art to the claimed invention. Accordingly, withdrawal of the anticipation rejection is solicited.

***Double Patenting Rejection:***

On pages 5-7 of the office action, the examiner maintains the provisional rejection of the claims 124-127 under the judicially created doctrine of obviousness-type double patenting and alleges as being unpatentable over claims 124-129, 131-134, and claims 124-125, 130, 143-146 of co-pending application serial nos. 10/197,209 and 09/764,445, respectively. In response, applicants submit, because applicants have not received any notice of allowance for the '209 or the '445 applications, the merits of this provisional rejection need not be discussed by at this time. See MPEP § 822.01 (Rev. 5, August 2006). More specifically, in this context, applicants refer the examiner to the MPEP § 804 I.B. that states:

*B. Between Copending Applications-Provisional Rejections*

Occasionally, the examiner becomes aware of two copending applications that were filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee, or that claim an invention resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3), that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications ( 35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

Accordingly, the provisional double-patenting rejection over the co-pending application serial nos. 10/197,209 and 09/764,445 should be withdrawn.

**REQUEST**

Applicants submit that claims 124-129 are in condition for allowance, and respectfully request favorable consideration to that effect so that an interference can be declared with applicants as the senior party by virtue of the priority afforded by the priority applications. The examiner is invited to contact the undersigned at 202-654-6200 should there be any questions.

Respectfully submitted,



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Date

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